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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,156	06/29/2000	Marcel Loetscher	2225.1001-009	8374

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/02/2003

98

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/607,156

Applicant(s)

LOETSCHER ET AL.

Examin r

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,17,19-21 and 60-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-21, 60, 63, 64, 69-76, 81-84, 87, and 88 is/are allowed.
- 6) ☒ Claim(s) 16,17,61,62,65-68,77-80,85 and 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 24 March 2003 is acknowledged. Claims 16, 17, 19-21, and 60-88 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejection of claims 16, 17, and 61-84 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

New Grounds of Rejection

3. On consideration, the rejection of claims 16 and 17 under 35 U.S.C. 102(a) as anticipated by Marchese et al., made of record in the office action of paper no. 5 and withdrawn in the office action of paper no. 8, is reapplied to these claims. Marchese et al. teaches a polynucleotide that encodes a G-protein coupled receptor, GPR9. This polynucleotide is 71.1% identical to instant SEQ ID NO: 1 and the region from about residue 110 to residue 1293 is identical to region from about residue 102 to residue 1275 of the instant sequence. Thus the polynucleotide taught by Marchese et al. would be expected to bind to SEQ ID NO: 1 under conditions of stringent hybridization. The protein encoded by the polynucleotide taught by Marchese et al., according to Applicant's statement on p. 17 of paper no. 7, differs from instant SEQ ID NO: 2 in that it lacks the four N-terminal amino acids of SEQ ID NO: 2. The protein taught by Marchese et al. is thus presumed to bind IP-10 and MIG and have the same downstream effects as the protein of SEQ ID NO: 2, absent any evidence to the contrary. Thus the polynucleotide taught by Marchese et al. anticipates the limitations of claims 16 and 17.

Applicant's arguments with respect to the rejection of paper no. 5, of record in the amendment of paper no. 7, are addressed in paragraph 6 below as they relate to the current rejection under 35 U.S.C. 102(a) and the rejection under 35 U.S.C. 103(a) in the following paragraphs. Arguments not relevant to the current rejection are not addressed.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 61, 62, 65-68, and 77-80, 85 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchese et al. in view of Sambrook et al. (Molecular Cloning, 1989).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Marchese et al. teaches as set forth above but fails to teach such modifications as fusion proteins and detectable labels. Such modifications are taught by Sambrook et al. on, for example, pp. 17.2 and 18.6 as tools for producing antibodies and for investigating protein function. It would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Marchese et al. with those of Sambrook et al. to produce fusion proteins and detectably labeled proteins. One of ordinary skill would have been motivated to do so because

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Marchese et al. teaches on pp. 343-344 that it is desirable to identify ligands, structural features, and functions of GPR9 and Sambrook et al. teaches that fusion proteins and detectable labels are useful for functional analysis of proteins.

6. Applicant has argued in paper no. 7 that Marchese et al. only speculate that GPR9 binds chemokines. Applicant has further argued that it was unclear whether part of the molecule taught by Marchese et al. was missing and whether the missing portion was required for ligand binding. Applicant has stated that N termini are highly divergent and important for ligand binding and that one of ordinary skill would have known that, and that there is thus no reason to conclude that the GPR9 polypeptide would inherently bind IP-10 and MIG.

Applicant's arguments have been fully considered but have not been found to be persuasive. It is not necessary that an inherent property be recognized in order for an invention to be anticipated. If the molecule disclosed by Marchese et al. was able to bind IP-10 and MIG, it was able to do so regardless of whether that ability was recognized at the time. The speculations of Marchese et al. and the conclusions of the artisan of ordinary skill do not affect the inherent properties of a protein. While Applicant states that N termini are "highly divergent", the divergence between the protein of Marchese et al. and that of Applicant is a truncation of only four amino acids; the remaining 360 are identical. MPEP §2112.02 states

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

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It is maintained that a protein that lacks only the 4 N-terminal amino acids of a total of 364 is “substantially identical in structure” to the longer protein. Applicant has provided no showings that the binding characteristics are different, but merely arguments as to why they might not be. Thus Applicant’s arguments are not sufficient to overcome the conclusion that the protein taught by Marchese et al. meets the limitations of claims 16 and 17, thus also rendering the modifications of claims 61, 62, 65-68, and 77-80, 85 and 86 obvious in view of Sambrook et al.

CLAIMS 19-21, 60, 63, 64, 69-76, 81-84, 87, AND 88 ARE ALLOWED. CLAIMS 16, 17, 61, 62, 65-68, 77-80, 85 AND 86 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

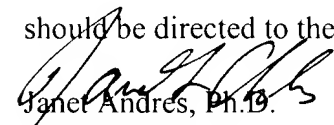
Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly

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signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Janet Andres, Ph.D.
Patent Examiner

July 1, 2003